

LISTING OF THE CLAIMS:

This listing of claims will replace all prior versions, and listings, of claims in the application:

1. (Currently Amended): ~~Process A~~ a process for preparing ~~a active~~ polymer extrudate comprising a polymer matrix and a guest matter, the process comprising:

contacting a polymer substrate and a guest matter with a supercritical fluid under supercritical conditions of elevated temperature and/or pressure to plasticise the polymer substrate and to incorporate the guest matter and

extruding the polymer substrate ~~incorporating and the~~ guest matter under supercritical conditions via an extrusion orifice into a collection zone or a mould with simultaneous or subsequent release of pressure, ~~whereby~~ wherein

the polymer extrudate is obtained comprising a solid admixture of the polymer matrix and the guest matter in form conferred by the orifice or the mould and wherein the extrudate is ~~in the form of~~ formed as sheets, films, tubes, cylinders, rods, ribbons, fibrils, filaments, fibroids or fibres.

2. (Currently Amended): ~~Process for preparing active polymer extrudate comprising polymer matrix and guest matter, the~~ The process as claimed in Claim 1, comprising contacting a polymer substrate and a guest matter with a supercritical fluid under supercritical conditions of elevated temperature and/or pressure to plasticise the polymer substrate and incorporate guest matter and extruding polymer substrate incorporating guest matter under supercritical conditions

~~via an extrusion orifice into a collection zone or a mould with simultaneous or subsequent release of pressure, whereby extrudate is obtained comprising a solid admixture of polymer matrix and guest matter in form conferred by the orifice or the mould wherein the extrudate is in the form of~~ formed as sheets or films.

3. (Currently Amended): ~~Process~~ The process as claimed in Claim 1, ~~wherein the or 2 for preparing~~ extrudate is suitable for topical, rectal, parenteral, mucosal, epicutaneous, subcutaneous, intravenous or intrarespiratory application route or as a structural implant in the human or animal body or in living matter.

4. (Currently Amended): ~~Process according to any of Claims 1 to 3~~ The process as claimed in Claim 1, wherein the process is conducted in the substantial absence of an additional solvent.

5. (Currently Amended): ~~Process according to any of Claims 1 to 4~~ The process as claimed in Claim 1, wherein the process is conducted at a temperature ~~in the range from~~ 30°C to 55°C and less than or equal to 140°C.

6. (Currently Amended): The process as claimed in Claim 1, wherein the ~~Process for preparing active polymer extrudate comprising polymer matrix and guest matter, the process comprising contacting a polymer substrate and guest matter with a supercritical fluid under supercritical conditions of elevated temperature and/or pressure to plasticise the polymer substrate and incorporate guest matter and extruding polymer substrate incorporating guest~~

~~matter under supercritical conditions via an extrusion orifice into a collection zone or a mould~~  
~~with simultaneous or subsequent release of pressure, whereby~~ extrudate is obtained comprising a  
solid admixture of polymer matrix and guest matter in form conferred by the orifice or the mould  
in the form of tubes, cylinders, rods, ribbons, fibrils, filaments, fibroids or fibres and wherein  
~~characterised in that~~

the process is conducted at a temperature from 30°C to 55°C ~~and less than or equal to~~  
140°C and less than the T<sub>g</sub>, T<sub>m</sub> or non-viscous state of the polymer substrate.

7. (Currently Amended): The process as claimed in Claim 1, wherein the molecular  
weight of the ~~Process according to any of Claims 1 to 6 conducted with~~ polymer substrate of  
~~molecular weight is in the a range from~~ 20 to 50 kDa ~~or 50 to 200 kDa.~~

8. (Currently Amended): ~~Process as claimed in any of Claims 1 to 7~~ The process as  
claimed in Claim 1, wherein two or more polymer types are contacted with the supercritical  
fluid as discrete components and co-extruded, ~~the to form a composite~~ extrudate ~~having~~  
comprising two or more polymer layers or zones.

9. (Currently Amended): The process as claimed in Claim 1, wherein the guest  
matter comprises a first ~~Process as claimed in any of Claim 1 to 8 comprising plural guest~~  
~~entities comprising~~ guest matter of one type for one intended function ~~together with~~ and a second  
guest matter of another type for ~~[[a]]~~ same or different intended function, ~~for example one or~~  
~~more drugs and one or more excipients.~~

10. (Currently Amended): The process as claimed in Claim 1, wherein the orifice has  
~~Process according to any of Claims 1 to 9 conducted with orifice dimensions in the a range of~~  
0.001-10 millimetre, ~~preferably 0.001-2 millimetre~~ and length in ~~the a range of~~ 0.1 millimetre to  
1 meter.

11. (Currently Amended): The process as claimed in Claim 1, wherein the orifice has  
an Process according to any of Claims 1 to 10 conducted with orifice of increasing dimension  
along its length, ~~preferably increasing at a first angle with respect to the axis and optionally at a~~  
~~second angle in respect to the axis at the orifice outlet.~~

12. (Currently Amended): The process as claimed in Claim 1, Process as claimed in  
~~any of claims 1 to 11 wherein an the~~ orifice is one of a plurality of orifices which ~~may be~~ are  
independent or which ~~may be~~ are adjacently or coaxially or concentrically aligned to form a  
plurality of simple extrudates or to form a composite extrudate ~~as hereinbefore defined~~, and ~~may~~  
additionally or alternatively comprise a solid core ~~or the like, whereby to form a hollow~~  
~~extrudate is obtained for example an annular orifice may provide tubes or cylinders.~~

13. (Currently Amended): ~~Process according to any of Claims 1 to 12~~ The process as  
claimed in Claim 1, wherein extrusion is into a the polymer substrate and the guest matter are  
extruded into the collection zone at positive, ambient or negative pressure, which may be greater  
~~or less than the supercritical pressure and is preferably in the range 50 to 140 bar or in the range~~  
~~1 to 50 bar.~~

14. (Currently Amended): ~~Process according to any of Claims 1 to 13~~ The process as claimed in Claim 1, wherein the polymer substrate is selected from ~~any an~~ an amorphous polymer, a semi-crystalline polymer or a crystalline polymer, ~~suitably polymers such as~~ polyesters, poly(ortho esters), polyanhydrides, poly(amino acids), poly(pseudo amino acids), polyphosphazenes, azo polymers; vinyl polymers poly(acrylic acid), poly(methacrylic acid), polyacrylamides, polymethacrylamides, polyacrylates, Poly(ethylene glycol), Poly(dimethyl siloxane), Polyurethanes, epoxy, bis maleimides, methacrylates such as methyl or glycidyl methacrylate, Polycarbonates, Polystyrene and derivatives; carbohydrates, polypeptides and proteins; and copolymers thereof.

15. (Currently Amended): ~~Process according to any of Claims 1 to 14~~ The process as claimed in Claim 1, wherein the guest matter is selected from ~~biofunctional or non biofunctional~~ material including but not limited to:

- (1) (pharmaceutical) drugs and veterinary products;
- (2) agrochemicals as pest and plant growth control agents;
- (3) human and animal healthcare products;
- (4) human and animal growth promoting, structural, or cosmetic products including products intended for growth or repair or modelling of the skeleton, organs, and dental structure ~~and the like~~;
- (5) absorbent biofunctional materials for poisons[[,]] and toxins ~~and the like~~;
- (6) ~~functioning matter such as any~~ nutrient dependent, biological matter which is characterised by replication, division, regeneration, growth, or proliferation ~~or the like~~;
- (7) organic or inorganic materials for use in dyeing, constructing textiles, and electronic materials ~~and the like~~;
- (8) SMART materials; or
- (9) formulating agents which stabilise or enhance the guest matter. ~~functional material.~~

16. (Currently Amended): ~~Process~~ The process as claimed in Claim 1, ~~any of claims 1 to 15~~ wherein the guest matter is present in an amount of  $1 \times 10^{-12}$  ~~to  $1 \times 10^{-6}$  or  $1 \times 10^{-6}$~~  to 1 wt%, more preferably in low volumes in the range  $1 \times 10^{-12}$  ~~to  $1 \times 10^{-9}$ ,  $1 \times 10^{-9}$  to  $1 \times 10^{-6}$~~  or 0.01 or 0.1 to 1 wt%.

17. (Currently Amended): ~~Process~~ The process as claimed in Claim 1, ~~any of claims 1 to 15~~ wherein the guest matter is present in an amount of 1.0 wt% up to 50 wt%,

18. (Currently Amended): ~~Polymer~~ A polymer extrudate comprising polymer matrix and guest matter produced by the process as claimed in Claim 1, wherein ~~as hereinbefore defined in any of Claims 1 to 23 as a solid admixture in extrudate form in the form of the extrudate is formed as~~ tubes, cylinders, rods, ribbons, fibrils, filaments, fibroids or fibres, and wherein the polymer matrix comprises a polymer ~~of having a molecular weight in the range in a range from~~ 20 to 50 kDa ~~or 50 to 200 kDa~~.

19. (Currently Amended): ~~Polymer~~ The polymer extrudate as claimed in Claim 18 suitable for topical, rectal, parenteral, mucosal, epicutaneous, subcutaneous, intravenous or intrarespiratory application route or as a structural implant in the human or animal body or in living matter wherein the guest matter is present in an amount of  $1 \times 10^{-12}$  to 1 wt%,  $1 \times 10^{-6}$  ~~or  $1 \times 10^{-6}$  to 1 wt%~~, more preferably in low volumes in the range  $1 \times 10^{-12}$  to  $1 \times 10^{-9}$ , ~~to  $1 \times 10^{-6}$  or 0.01 or 0.1 to 1 wt%~~.

20. (Currently Amended): ~~Polymer~~ The polymer extrudate as claimed in Claim 18 suitable for topical, rectal, parenteral, mucosal, epicutaneous, subcutaneous, intravenous or intrarespiratory application route or as a structural implant in the human or animal body or in living matter wherein the guest matter is present in an amount of 1.0 wt% ~~up~~ to 50 wt%.

21. (Currently Amended): An apparatus for ~~Apparatus for use in the preparation of polymer extrudate using~~ carrying out the process as claimed in Claim 1, the apparatus ~~hereinbefore defined in any of Claims 1 to 17~~ comprising

a pressure vessel adapted for temperature and pressure elevation, ~~elevation which may comprise means for mixing the contents, and wherein the pressure vessel includes~~ comprising means for extruding the polymer substrate and the guest matter ~~contents~~ via an orifice as ~~hereinbefore defined~~ into a second collection vessel at a lower pressure.

22. (Currently Amended): ~~Extrudate~~ The polymer extrudate as claimed in ~~any of Claim 18 to 20 or a composition thereof or a product of the process as claimed in any of Claims 1 to 17~~ for use as a controlled release device ~~such as a drug delivery device; in Pharmaceutical or Veterinary applications for example as a human or animal health or growth promoting structural or cosmetic product, natural or artificial implant, drug delivery or DNA delivery device; as an anti-microbial application; for example having bacteria static or cidal activity; as a natural or synthetic barrier capable of immobilising e.g. naturally occurring or artificially introduced poisons or toxins by e.g. absorption, interaction or reaction; in Agrochemical or crop protection applications; in the processing of thermally labile fibres for use in dyeing, textiles, electronics etc~~ below the polymer T<sub>g</sub>, T<sub>m</sub> or melt viscosity; in incorporation of dyes and other thermally labile

materials into polymers that cannot be formed by traditional processes ~~e.g. melt extrusion and the like~~; or in incorporation of surfactants into fibres to control polymer properties.

23. (Currently Amended): ~~Process~~ A process for preparing a polymer extrudate, the process comprising:

contacting a polymer substrate with a supercritical fluid under supercritical conditions of elevated temperature and/or pressure to plasticise the polymer substrate and

extruding the polymer substrate under supercritical conditions via an extrusion orifice into a collection zone or a mould with simultaneous or subsequent release of pressure, ~~whereby~~ wherein

the extrudate is obtained in form conferred by the orifice or the mould in the form of sheets, films, tubes, cylinders, rods, ribbons, fibrils, filaments, fibroids or fibres, and wherein characterised in that

the process is conducted at a temperature of 30°C to ~~55°C and less than or equal to~~ 140°C.

24. (Currently Amended): ~~Process~~ The process as claimed in Claim 23, wherein the ~~for preparing polymer extrudate comprising contacting a polymer substrate with a supercritical fluid under supercritical conditions of elevated temperature and/or pressure to plasticise the polymer substrate and extruding polymer substrate under supercritical conditions via an extrusion orifice into a collection zone or a mould with simultaneous or subsequent release of pressure, whereby~~ extrudate is obtained in form conferred by the orifice or the mould in the form



of sheets or films characterised in that the process is conducted at temperature of 30°C to 55°C and less than or equal to 140°C.

25. (Currently Amended): ~~Process~~ The process as claimed in claim 23 ~~or 24~~ wherein the polymer substrate comprises a labile polymer, ~~for example, poly(acrylonitrile) and copolymers thereof.~~

26. (New): The process as claimed in Claim 9, wherein the first guest matter comprises one or more drugs and the second guest matter one or more excipients.

27. (New): The process as claimed in Claim 13, wherein the polymer substrate and the guest matter are extruded into the collection zone at a pressure from 1 to 140 bars.

28. (New): The process as claimed in Claim 14, wherein the polymer substrate comprises polyesters, poly (ortho esters), polyanhydrides, poly(amino acids), poly(pseudo amino acids), polyphosphazenes, azo polymers; vinyl polymers, poly(acrylic acid), poly(methacrylic acid), polyacrylamides, polymethacrylamides, polyacrylates, oly(ethylene glycol), poly(dimethyl siloxane), polyurethanes, epoxy, bis-maleimides, methacrylates, polycarbonates, polystyrene and derivatives; carbohydrates, polypeptides and proteins; or copolymers thereof.

29. (New): The process as claimed in claim 25, wherein the polymer substrate comprises poly(acrylonitrile) or copolymers thereof.